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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,858	12/18/2001	Graham Stanley Leonard	P31220X2C2	1864
20462	7590	05/03/2004	EXAMINER	
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2220 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			SHEIKH, HUMERA N	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 10/024,858	<b>Applicant(s)</b> LEONARD ET AL.	
	<b>Examiner</b> Humera N. Sheikh	<b>Art Unit</b> 1615	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 11 December 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: \_\_\_\_\_.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s): \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because:

The Applicants' argument that the 'claims require that the formulations be both controlled and delayed' is relative and not defined. The argument that the 'claims do not permit any oral paroxetine formulation that comprises enteric coatings, as urged by the Examiner' is also not persuasive since the instant claims utilize "comprising" claim language and thus the "comprising" claim language permits this scope. The argument that 'the citation of WIPO 92/09281 is not pertinent to the issue of enablement' is not persuasive since the WIPO reference shows the state of the art and what is taught in the art. For the Applicants' request to explain how claim 26 is rejected under 112 and 102 it is the Examiner's position that 'undue experimentation' is used to establish the scope of the claim. A reference that anticipates a single concept has no bearing on the 112 enablement as long as the reference is not as broad as the claims. Regarding the argument on page 5, section (1) that 'how an enteric coating over an immediate release oral formulation containing paroxetine could be covered by the instant claims', it is noted that the "comprising" permits this scope absent the recitation of distinct rates of release. For arguments (2) and (3) on page 6, see previous paragraph. Applicants' arguments against the 102(b) reference are summarized as being the prior art fails to specifically teach the mechanism described in Applicant's specification. It is not necessary for the prior art to be aware of the specific mechanism to anticipate the invention, merely that the claimed limitations be suggested is sufficient. For the argument that "may if desired" falls short of the statutory requirements for anticipation under 102, the "may if desired" is a suggestion that cannot be ignored in the art. The argument that Johnson teaches "by any route" is not persuasive since the teachings are sufficient to anticipate the broad invention claimed. When Applicant presents broad claims, the Examiner should not be limited to the scope of the invention disclosed in the specification.

  
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